REMARKS

Claims 37-49 are pending. In this amendment, claims 40 and 43 are now set forth in independent form and should be deemed allowable, as should all claims dependent thereon, i.e., claims 41, 42, and 44-48.

Claims 39 and 49 are rejected under 35 U.S.C. § 112, second paragraph, as well as under 35 U.S.C. § 102(b). Claims 37 and 39 have been rejected under 35 U.S.C. § 103. All rejections have been considered, and are traversed.

Applicants submit herewith a Declaration by one of the inventors, Dr. Ursula-Henrike Wienhues-Thelen. Dr. Wienhues-Thelen discusses the difference between the reference relied upon in the rejection under 35 U.S.C. § 102(b), and the claims to which it is applied. Attention is drawn, for example, to points 6 and 7 of the Declaration, as well as to point 8, referring to evidence supporting the statements made in points 6 and 7.

All of the references referred to in point 8 have been made of record in either the present case, or one of the applications in the series of applications leading to this one. As such, copies have not been provided at this time, on the assumption that they are available to the Examiner; however, should this assumption be incorrect, and any or all of the references are requested, copies will be provided.

In brief, JP '965 does not teach or suggest how to detect early seroconversion antibodies. As the references referred to show, the antibody profile of a patient suffering from HCV changes over the course of the infection. Early seroconversion antibodies differ markedly from those at a later stage. For example, the high prevalence of IgM antibodies at early seroconversion is not characteristic of a later stage of infection. In addition, the specificity of the early stage antibodies differs from the affinity of later stages, as the references show.

Turning to the rejections under 35 U.S.C. § 103, it is first of all pointed out that claim 37 now refers specifically to humans. As the Examiner has expressly stated that *Beach* has been withdrawn from claims reciting human, the rejection of claim 37 will now be assumed to be over *Vallari*. The rejection of claim 38 combines *Vallari* and *Schuurs*.

Vallari actually suggests that one would assay for antibodies to the "core" antigen, i.e., c100 or NS4, rather than NS3. Please see page 555, "Discussion":

> "The earliest antibody response to HCV was detected most frequently by the core antigen..."

If the core antigen is a superior marker, why would one start with NSD? Further, there is no suggestion within *Vallari* that a change in the nucleic of the assay, i.e., the use of reducing conditions in the assay, would change its sensitivity. Indeed, *Vallari* suggests hat an unmodified assay for c100 is all that is necessary. There is no motivation to use reducing conditions.

The Examiner's attention is directed to point 10 of the Declaration in this regard.

In view of the foregoing, as well as the references cited in point 8 of the Declaration, it is believed that the obviousness rejection cannot be maintained.

Finally, turning to the rejection under 35 U.S.C. § 112, while applicants' appreciate the Examiner's concern that a two step process is necessary to detect seroconversion, as has been pointed out, the antibody profile of a seroconversion is very different from that at any other time. If the antibodies characteristic of seroconversion are present, this marker, *per se*, is sufficient. As such, additional steps are not required in the assay. Please see, e.g., point 6 of the accompanying Declaration.

In view of the foregoing, withdrawal of the rejection under 35 U.S.C. § 112 is believed proper and is urged..

All rejections have been addressed. Allowance is now believed proper.

Respectfully submitted,

FULBRIGHT & JAWORSKI L.L.P.

By _____
Norman D. Hanson
Reg. No. 30,946

666 Fifth Avenue
New York, NY 10103
212-318-3168
212-318-3400 (fax)